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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,193	08/29/2001	Kenneth M. Riff	P-9618.00	8485

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EXAMINER	
FRENEL, VANEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,193	RIFF ET AL.	
	Examiner	Art Unit	
	Vanel Frenel	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,12,13,18-21,32-34,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12,13,18-21,32-34,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Amendment filed on 04/05/05. Claims 14-17, 22-31, 35-38, and 41-74 have been cancelled. Claims 8, 18, 33, 39 and 40 have been amended. Claims 1-8, 12-13, 18-21, 32-34, 39-40 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-21 and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maus et al (6,602,469) in view of Cofano et al (2002/0059587) and further in view Kumar et al (6416471), for substantially the same reasons given in the previous Office Action, and incorporated herein.

(A) Claims 8 and 18 have been amended to recite the limitations of "implantable", "implanted" and "implantable". However these limitations have been clearly shown (in, Col.3, lines 21-65 of Kumar).

One of ordinary skill in the art at the time of the invention would have found it obvious to include the system of Kumar within the collective teachings of Maus and Cofano with the motivation of providing a portable physiological data monitoring/alert system in which one or more patients wear sensor harnesses including a microprocessor which detects potentially life-threatening events and automatically calls a central base station via radiotelemetry using a radio modem link (See Kumar, Col.3, lines 5-12).

(B) Claims 33 and 39 have been amended to recite the limitations of "having implantable medical devices", "implanted", "implanted" and "and". However, these limitations have been clearly shown in Col.3, lines 5-67 of Kumar.

One of ordinary skill in the art at the time of the invention would have found it obvious to include the system of Kumar within the collective teachings of Maus and Cofano with the motivation of providing a portable physiological data monitoring/alert system in which one or more patients wear sensor harnesses including a microprocessor which detects potentially life-threatening events and automatically calls a central base station via radiotelemetry using a radio modem link (See Kumar, Col.3, lines 5-12).

(C) Claim 40 has been amended to recite the limitations of "implanted medical device of the". However these limitations have been rejected for the same reasons given in claims 8, 18, 33 and 39, and incorporated herein.

(D) Claims 1-7, 12-13, 19-21, 32 and 34 have not been amended. Therefore they are rejected for the same reasons given in the previous Office Action and incorporated herein.

Response to Arguments

4. Applicant's arguments filed 04/05/05 with respect to claims 8, 18, 33, 39 and 40 have been fully considered but they are not persuasive. Applicant 's arguments will be addressed hereinbelow in the order in which they appear in the response filed on 04/05/05.

(A) At pages 10-12, Applicant argues the followings:

(1) Maus fails to disclose monitoring data packages to determine revenue for the service.

(2) None of the reference alone or in combination teach the communication platform, protocols and requirements necessary to receive data from an implantable medical device and provide such information to the claimed network.

(3) None of the reference alone or in combination teach collecting data from implantable medical devices and making such information available through a web site or similar portal.

(4) None of the references alone or in combination render the pending claims obvious.

(B) With respect to Applicant first argument, Examiner respectfully submits that Cofano discloses 0015] "The above and other objects of the invention are accomplished

by an apparatus implementing a method which allows a remote user, such as an employee, to communicate with a service provider, such as a healthcare provider. In one implementation, the employee and the service provider can communicate via e-mail and videoconferencing through the Internet. A secured intranet server is also provided. The intranet server provides transaction assistance to the service provider and forwards provider recommendations to the employee. The employee can forward feedback, such as service provider performance and quality information, to the intranet server where such data can be stored. In accordance with the invention, the server can store and track data to allow organizations to quantify benefits issues and problems, do outcomes research, monitor benefit service quality information, insert reminders onto employers' calendars, develop rules for service delivery, update directories and provide targeted service information. According to the invention, authorized service providers and information content providers can access the intranet server to place content on the system and to receive feedback information on performance and quality of service. The secure server also allows benefits managers to use the system to collect data for billing purposes and for analyzing the benefits concerns of the workforce. Moreover, the system according to the invention allows researchers to access the database developed on the intranet server in order to perform complex studies of the user population. Such studies could be performed for the benefits administrators or could be independent studies. Benefits administrators could charge for access to the data for independent studies, thereby creating a revenue stream that helps fund such a benefits system"

which correspond to claimed feature (See Cofano, Page 2, Paragraph 0015). Therefore, Applicant's argument is non-persuasive.

(C) With respect to Applicant second and third argument, Examiner respectfully submits that Kumar discloses "Bornn et al. describe a portable physiological data monitoring/alert system in U.S. Pat. Nos. 4,784,162; 4,827,943; 5,214,939; 5,348,008; 5,353,793; and 5,564,429 in which one or more patients wear sensor harnesses including a microprocessor which detects potentially life-threatening events and automatically calls a central base station via radiotelemetry using a radio modem link. In a home or alternate site configuration, communications between the base station and remote unit is by way of commercial telephone lines. Generally, the system automatically calls "911" or a similar emergency response service when an abnormality is detected by the ECG monitor. Unfortunately, the sensor harness is quite cumbersome and conspicuous and includes sensors for performing an alert function rather than data collection and analysis functions.

Segalowitz discloses a wireless vital signs monitoring system in U.S. Pat. Nos. 4,981,141; 5,168,874; 5,307,818; and 5,511,553 including a precordial strip patch including a multi-layer flexible structure for telemetering data by radio frequency or single wire to hardware recording apparatus and a display monitor. Microsensors and conductive contact elements (CCEs) are mounted on the strip patch so as to permit simultaneous and continuous detection, processing and transmission of 12-lead ECG, cardiac output, respiration rate, peripheral blood oximetry, temperature of the patient,

and ECG fetal heart monitoring via a single wavelength of radio frequency transmission. While the precordial strip patch used by Segalowitz purportedly transmits vital signs data up to 50 meters, it requires a dual-stage operational amplifier chip, an encoder modulator chip, a wireless transmitter chip including an oscillator, and other costly components such as artificial intelligence software, sound and visual alarms, and a microprocessor. As a result, the precordial strip patch is relatively expensive to manufacture and operate. Also, as with the other telemetry systems noted above, the emphasis of Segalowitz is on real-time monitoring and alerting of medical personnel to immediate medical needs of the patient.

Platt et al. also disclose a sensor patch for wireless physiological monitoring of patients in U.S. Pat. No. 5,634,468. Platt et al. describe a sensor and system for monitoring ECG signals remotely from patients located in non-hospital sites. In this system, a sensor patch containing sensing electrodes, signal processing circuitry and radio or infra-red transmission circuitry is attached to the patient's body and preferably worn for at least a week before its power supply is exhausted and the sensor patch is thrown away. A receiver at a primary site in the vicinity of the patient receives the data transmitted by the sensor patch and stores the sensed data. When the patient feels discomfort or concern, or if the portable unit sounds an alarm, the patient telephones the monitoring station and downloads the stored data from the portable unit via the standard voice telecommunications network. The downloaded ECG data is then monitored and analyzed at the monitoring station. The receiver in the proximity of the patient may be a portable unit carried around by the patient, where the portable unit

includes a receiver, a processor for processing the received data to identify abnormalities, a memory for storing the sensed data, and circuitry for interfacing to a telephone line to send the ECG data signals to the monitoring station. The monitoring station decodes the received ECG signals and performs beat and rhythm analysis for classification of the ECG data. If an abnormal condition is discovered, medical personnel in the vicinity of the patient are contacted. While the system described by Platt et al. may collect ECG data from the patient and process it at a remote monitoring station, the data is only collected when the patient initiates the data download. Otherwise, data is lost once the memory in the portable unit is full. No mechanism is provided for continuously collecting data, at all times, in a way which requires no patient action" which correspond to Applicant's claimed feature (See Kumar, Col.3, lines 6-67 to Col.4, line 11). Therefore, Applicant's argument is non-persuasive.

(D) With respect to Applicant fourth argument, Examiner respectfully submits that obviousness is determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. See *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685,686 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785,788 (Fed. Cir. 1984); and *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143,147 (CCPA 1976). Using this standard, the Examiner respectfully submits that he has at least satisfied the burden of presenting a *prima facie* case of obviousness, since he has presented evidence of corresponding claim elements in the prior art and has expressly articulated the combinations and the motivations for combinations that fairly suggest. Moreover, in

the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references are accompanied by select portions of the respective reference(s) which specifically support that particular motivation and/or an explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and reasons indicated by the Examiner, *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

In response to Applicant's concern that the Examiner have ignored the mandate of the modern case law which clearly and explicitly hold that in order for the references to be combined in that the references must explicitly teach or suggest every element of the combination as well as how to use such a combination, the Examiner respectfully submits that Applicant misinterprets the some of the case law cited. For example, the Court in *In re Fritch* stated "[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. [emphasis added]" *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988). Each applied reference does not expressly suggest combination with the other respective references; however, the Examiner has shown that motivation for combining the references existed in the prior art. The "modification" referred to in *In re*

Fritch involves extensive changes to the primary references. Such is not the case in the present combinations, where all modifications proposed by the Examiner are specifically taught by the references and that knowledge generally available to one of ordinary skill in the art. Therefore, the combination of references is proper and the rejection maintained.

In addition, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. However, although the Examiner agrees that the motivation or suggestion to make modifications must be articulated, it is respectfully contended that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek*, 163 USPQ 545 (CCPA 1969).

The Examiner is concerned that Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re DeLisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti et al*, 192 USPQ 278 (CCPA) that:

(i) obviousness does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references, but what they would suggest. Therefore, Applicant's argument is not persuasive.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is571-272-6769. The examiner can normally be reached on Monday-Thursday from 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

V.F
V.F

June 23, 2005

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER